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EXAMINER

WESSENDORF, TERESA D

ART UNIT

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1639

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



Continuation of Disposition of Claims: Claims pending in the application are 1-16,93-101,106,107,112-133,138-159,162,164,165,167,169,171,173-175,177,181-186,188 and 193-197.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 12-16, 93-101,106, 107, 112-133, 138-140, 142-159, 162, 165, 167, 171, 175 and 196-197 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-165, 167, 169-171,173-175, 177, 178, 181-186, 188, and 193-197 .

***DETAILED ACTION***

***Claims Status***

Claims 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-165, 167, 169, 171, 173-175, 177, 181-186, 188, and 193-197 are pending.

Claims 12-16, 93-101, 106, 107, 112-133, 138-140, 142-159, 162, 165, 167, 171, 175 and 196-197 1-16, 93-101, 106, 107, 112-133, 138-159, 162, 164-165, 167, 169-171, 173-175, 177, 178, 181-186, 188, and 193-197 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim.

Claims 1-11, 141, 164, 169, 173, 174, 177, 181-186, 188 and 193-195 are under consideration.

***Withdrawn Objection and Rejections***

In view of applicants' arguments and amendments to the claims, the rejections under 35 USC 101 and 35 USC 112, second paragraph have been withdrawn.

***Claim Rejections - 35 USC § 112***

Claims 1-11, 141, 164, 169, 173, 174, 177, 181-186, 188 and 193-195, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was

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not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record as reiterated below.

The claimed "comprises 61 kinases" is not supported in the as-filed specification. In the amendment of 11/8/2004, applicants amended the claims to contain this limitation. Applicants however failed to specifically point out where in the specification support for the new limitations can be found.

See MPEP 714.02.

MPEP § 2163.05 states "[t]he failure to meet the written description requirement of 35 U.S.C. 112, first paragraph, commonly arises when the claims are changed after filing to either broaden or narrow the breadth of the claim limitations, or to alter a numerical range limitation or to use claim language which is not synonymous with the terminology used in the original disclosure"

### ***Response to Arguments***

Applicants rely on Example I at pages 27-38 as support for the claimed 61 kinases. This is alleged to disclose the production of positionally addressable arrays comprising at least 122 yeast kinases. Applicants submit that the production of an array comprising 122 kinases clearly, must implicitly and inherently, encompass an array comprising 61 kinases.

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Furthermore, Applicants note the specification at page 11, lines 14-19, discloses the use of 50%, 75%, 90% or 95% of all of the expressed proteins with same type of biological activity in the genome of an organism. A person of ordinary skill in the art would readily recognize that 50% of 122 kinases is equal to 61 kinases, as recited in present claim 1. Applicants note that there is no in haec verba requirement of the written description requirement of 35 U.S.C. § 112, first paragraph, and that newly added claim limitations may be supported in the specification through express, implicit, or inherent disclosure. See M.P.E.P. § 2163(I)(B). Applicants note that the preparation of an array comprising 122 kinases must, at the very least implicitly and inherently, provide support for an array comprising 61 kinases. Furthermore, disclosure of arrays comprising 50% of 122 kinases (or 61 kinases) provides explicit support for the recitation of 61 kinases in present claim 1.

In response, applicants' arguments as to the production of positionally addressable arrays are not commensurate in scope with the claims. The claims recite an array. Furthermore, there is nothing in the disclosure that discloses of any range of kinase that can be placed on the array. If this is an

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implicit or inherent limitations is applicant then alleging that 1 to an infinite number of kinases can be placed onto the array? The term comprising is an open-ended language. Also, Example I, page 27 recites the 122 genes specifically from the yeast genome, not from the broad claimed any kinase from any type of organisms. Example I also discloses an encoded kinase of yeast and not an expressed one, as argued. Page 11 appears inconsistent with Example I, which discloses broadly expressed proteins, not encoding proteins from different types of the disclosed organism. The species yeast is not included in the lists of the broad proteins recited therein.

As MPEP § 2163.05 states "[t]he failure to meet the written description requirement of 35 U.S.C. 112, first paragraph, commonly arises when the claims are changed after filing to either **broaden or narrow the breadth of the claim limitations, or to alter a numerical range limitation or to use claim language which is not synonymous with the terminology used in the original disclosure.**" (Emphasis added).

Whether a limitation constitutes new matter or not is not whether one skilled in the art would know that 50% of 122 kinases is equal to 61 kinases, as recited in amended claim 1. Rather, whether the newly added claimed limitation of 61 kinases is present in the as-filed specification.

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Claims 1-11, 141, 164, 169, 173, 174, 177, 181-186, 188 and 193-195, as amended, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for yeast protein' kinases of the Ser/Thr and tyrosine kinase family, does not reasonably provide enablement for the broad scope of an array of 61 kinases and functional domain kinase from an organism as mammal, yeast or Drosophila. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons as repeated below.

The claimed array comprises a broad genus of compositions. The claimed different substances encompass any members of the protein kinase from the organism of 'mammal, yeast, or Drosophila' which is broader than the enabling disclosure. The claimed array represents enormous scope because the claims do not place any limitations on the kind, number and/or length of kinase either singly from one family of organism or a combination(s) from the different numerous recited organisms. The instant specification is directed to an array comprising a plurality of different yeast protein kinase, specifically 122 different yeast protein' kinases of the Ser/Thr and tyrosine kinase family members (see specification: example I, pg. 27,



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line 19 thru pg. 35, line 20; example II, pg. 41, line 19 thru pg. 43, line 6). The specification does not provide reasonable assurance to one skilled in the art that the 61 kinases found in the yeast could be found in any or all of the organisms such as mammals especially the functional domain thereof. It is not apparent from the specification whether the same number of kinases or the kind of kinases or functional domain thereof can be found in any other organisms and made into an array. It is not apparent from the disclosure as to the functional domain of the kinase and the specific function attributed to said kinase positioned on the array. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. In a highly unpredictable art, as biotechnology, where one cannot predict whether one species would be predictive to the huge scope of the claimed, one cannot make a priori statement without any experimental studies. Factors such as the compatibility of the array with the substrate and compounds disposed therein, the compounds disposed in the array and other unpredictable variables can affect the function of the compounds. Thus, one cannot predict from a single species its correspondence or extrapolation to the genus, as claimed.

***Response to Arguments***

Applicants note that the use of kinases from other organisms, including mammals and *Drosophila*, in the arrays of the presently claimed invention would not have required undue experimentation, but rather, simple, straightforward experiments. The protein kinases and functional kinase domains for use in the presently claimed invention are all well-known, well-characterized proteins that the ordinarily skilled artisan would easily comprehend.

In reply, attention is drawn to the instant disclosure at e.g., Example I which states that the tyrosine kinase family members do not exist although seven protein kinases that phosphorylate have been reported.

Applicants rely on the Hanks reference for its disclosure that "there are now hundreds of different members [of the kinase superfamily] whose sequences are known." Hanks and Hunter, page 576. Furthermore, kinases, for example serine kinases, were already readily recognized in 1995 by virtue of their conserved subdomains.

In reply, there is nothing in Hanks' reference that discloses these hundreds of kinases are from any mammals or *Drosophila* or from any other origin as broadly claimed.

Applicants state that methods that could be used to confirm kinase activity were well known as of the filing date of the present application (see e.g., Example I of present specification). Thus protein kinases, and functional kinase domains thereof, were well-known in the art at the time of filing the present application. Applicants submit therefore, that the state of the art in protein kinases at the time of filing of the present application was such that the ordinarily skilled artisan, possessing a typical level of skill in protein purification and analysis, would have readily recognized that the kinases of mammals, yeast and Drosophila could be readily identified.

In reply, applicants have not provided any evidence either in specification or prior art, except for the instant disclosure of yeast genome, of any other methods by which other kinases have been identified by the disclosed method.

Applicants state that the presently claimed invention does not require the arrays to comprise the same 61 kinases, but rather, to simply comprise at least 61 purified active kinases (or functional domains) of these organisms.

In response, the claims recite functional kinase domains hence, it is unclear as to how the array can simply comprise at least 61 kinases. There is nothing in the specification or prior

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art cited by applicants that the 61 kinase array contains combinations from the different types of organisms such as eukaryotic or prokaryotic, at the time of filing.

Applicants note that the present specification clearly provides numerous examples of methods for preparing the presently claimed positionally addressable arrays utilizing yeast protein kinases (see specification at pages 27-38). Based on the knowledge available in the art at the time of filing, specifically, the ability to identify and prepare purified protein kinases from yeast, mammals and *Drosophila*, in combination with the detailed directions provided in the specification, it would not have required undue experimentation to prepare arrays comprising the kinases from any of these organisms.

In reply, applicants have not specifically pointed out where in the present specification, except for the general statements made therein, an array from yeast, mammals and *Drosophila* has been taught.

The Examiner contends that, as the field of biotechnology is highly unpredictable, one cannot determine whether the generation of arrays comprising kinases of one organism (yeast) would be predictive of arrays comprising kinases of mammals or *Drosophila*. The present specification provides detailed methods

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for attaching kinases or functional kinase domains to the surface of a solid support (e.g., polydimethylsiloxane), for example, through the use of a 3-glycidooxypropyltrimethoxysilane linker (GPTS). Applicants submit that the source of the kinase would not have any effect on the ability to attach the proteins to the surface of a solid support. The fact that a yeast kinase can be attached in this manner would clearly provide sufficient guidance to a person of ordinary skill in the art to utilize the same methods for attaching a kinase from a mammal or *Drosophila*. Applicants submit that, attaching mammalian or *Drosophilian* kinases to a solid support, using the detailed methods disclosed in the present specification, would clearly be within the abilities of the ordinarily skilled artisan. The Examiner is reminded that the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See M.P.E.P. § 2164.01 (emphasis added).

In reply, attention is drawn to applicants' REMARKS made on 12/21/07 as to the high unpredictability in this art referencing two of the newly submitted art. Applicants submit that Anderson et al note that:

... protein microarrays have still not found widespread use, in part because producing them is challenging. Historically, it has required the high-throughput

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production and purification of protein, which then must be spotted on the arrays. Once printed, concerns remain about the shelf life of proteins on the arrays.

Shaw et al at page 1, third paragraph line 3, through the fourth paragraph states:

It was first thought that protein biochips would just be an extension of DNA microarrays, and that hasn't exactly panned out," says Bodovitz. That's because proteins have proven to be much trickier to work with in array format than their genomic counterparts. First of all, there are issues of stability. Membrane proteins, for example, make up the majority of potential drug targets, but their particularly challenging to stabilize. Then there's the choice of immobilization technique, which determines how well the target protein presents itself to the capture agent, and the problem of nonspecific binding. And of course, proteins are inherently unstable outside their natural habitat of living cells, making them much more challenging than DNA to tag and manipulate.

Applicants' statements above as to the skepticism in the art provide evidence as to the high unpredictability in the art. Thus, an enabling disclosure for a single species of a protein would not be enabling for the broad scope of other proteins.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102/ 35 USC § 103***

Claims 1-11, 141, 181-186, 188, and 193-195, as amended, are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Uetz et al (Nature, 2/10/2000). (Based on the claimed interpretation of kinase present in a single organism and positioned in an array) for reasons as reiterated below.

Uetz et al, throughout the reference, teach a protein array representing yeast genome encoded proteins (see Abstract of the reference). The reference teaches fusing roughly 6000 potential ORFs (genes) from yeast genome (which comprises approximately 6000 genes) (see page 623, left col., 1st paragraph and page 624, left col. 2<sup>nd</sup> paragraph). Uetz teaches the yeast proteins were expressed in 96-well assay plates (page 624, left col., bottom of 2nd paragraph), which reads on a solid support of the addressable array of claim 1 because each well of the plates would have defined (or addressable positions). The reference also teach each of the protein encoded by a gene is expressed individually in individual

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wells of the plates as shown in Figure 1 of the reference (page 624), which reads on each protein being at a different position on a solid support of claim 1, for example. The claimed kinase present in the array would have been inherent to the yeast array taught by Uetz since yeast inherently contain kinase in its structure or would have been obvious to determine given the identified genome of yeast as taught by Uetz.

Where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972); *In re Best* 195 USPQ 430 (CCPA 1977).

### ***Response to Arguments***

Applicants submit that Uetz does not disclose the preparation of an array comprising purified active kinases, and hence, cannot anticipate the presently claimed invention. As set forth in the Methods section of Uetz, at page 627, the disclosed arrays were prepared by transferring patches of transformed yeast cells into wells



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of a micro- array assay plate. Uetz does not disclose any purification of the yeast proteins prior to placement in the assay plate, just simply transfer of the transformed cells. Hence, Uetz does not disclose the use of purified kinases or functional kinase domains, as recited in present claim 1.

In reply, applicants' arguments are not commensurate in scope with the claims. The claims are not drawn to a process or preparing an array, as argued. Rather to an array (product) itself.

Applicants note that, even assuming the arrays disclosed in Uetz comprise 61 kinases, there is no disclosure in Uetz sufficient to render obvious the construction of an array of at least 61 kinases or functional kinase domains, in which the array comprises kinases that are purified and active, as recited in present claim 1.

Applicants submit that, at the time of filing of the present application, it was unexpected that purified kinases and functional kinase domains of these kinases, could be purified and placed on a solid support to form an array, and that these kinases and kinase domains, would retain their kinase activity. It is only after the guidance provided in the present specification that a person of

ordinary skill in the art would consider it possible to generate the presently claimed arrays.

In reply, it is immaterial as to whether the product in the array is pure or not as much as the array is taught and known in the art. [See also applicants' statement above that the kinases are known (and an array at the time of applicants' invention is also known.)]

Applicants submit two references describing skepticism from those in the field regarding the preparation of protein arrays, even four years after the filing date of the present application.

In reply, obviousness does not require absolute predictability. Mere suggestion or implicit teachings suffice the finding of obviousness that array containing similar elements as claimed are taught in the art. As applicants stated above at the time of filing kinases are known, so is array. Thus, at the time of applicants' invention to place kinase on an array would be obvious to one having ordinary skill in the art as taught by Uetz.

Claims 1-11, 141, 164, 169, 173, 174, 177, 181-186, 188 and 193-195, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalon (WO 95/35505) in view of Felder

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et al (USP 6458533) or Lafferty(USP 6972183) for reasons as stated below.

Shalon discloses at e.g., page 12, lines 3-9:

A microarray as an array of regions having a density of discrete regions of at least about 100/cm<sup>2</sup>, and preferably at least about 1000/cm<sup>2</sup>. The regions in a microarray have typical dimensions, e.g., diameters, in the range of between about 10-250  $\mu$ m, and are separated from other regions in the array by about the same distance.

Shalon discloses at e.g., page 30, line 30 up to page 32, line 15:

Sheets of plastic-backed nitrocellulose where each microarray could contain, for example, 100 DNA fragments representing all known mutations of a given gene. The region of interest from each of the DNA samples from 96 patients could be amplified, labeled, and hybridized to the 96 individual arrays with each assay performed in 100 microliters of hybridization solution..... In addition to the genetic applications listed above, arrays of whole cells, peptides, **enzymes**, antibodies, antigens, receptors, ligands, phospholipids, polymers, drug cogener preparations....

Shalon discloses an array of enzymes and not kinase as claimed. However, Feder discloses at Example 18:

Kinases are enzymes that attach a phosphate to proteins. Many have been shown to stimulate normal and neoplastic cell growth. Hence, compounds that inhibit specific kinases (but not all kinases) can be used to test whether the kinases are involved in pathology and, if so, to serve as starting points for pharmaceutical development. For example, five tyrosine kinases that are involved in stimulating cell growth or in regulating the inflammatory

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response are src, lck, fyn, Zap70, and yes. Each kinase has substrates that are partially identified, as short peptides that contain a tyrosine. Some of the kinase specificities overlap so that different kinases may phosphorylate some peptides equally but others preferentially. For the five kinases, 36 peptide substrates are selected that show a spectrum of specific and overlapping specificities.

Lafferty discloses at e.g., col. 31, lines 41-49 the conventionality of an array containing substrate-enzymes such as kinase.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use in the array of Shalon the enzyme kinase as taught by Feder. Feder teaches that kinase have been shown to stimulate normal and neoplastic cell growth. To use the kinase in the array of Shalon would lead one having ordinary skill in the art in determining the kinase in the array responsible for neoplastic or normal cell growth. Furthermore, as taught by Lafferty an array containing a kinase is known in the art. [See also applicants' admission in the response at page 17 of the 12/19/2006 REMARKS]. Applicant states: compositions **utilizing well-known and well-characterized classes of proteins**, as in the presently claimed invention].

***Response to Arguments***

Applicants note that Shalon is primarily directed to arrays comprising polynucleotides (see Examples 1-3), and only mentions in passing that arrays comprising proteins and enzymes could be constructed. Furthermore, Felder discloses preparation of arrays comprising peptides that are substrates for kinases, not arrays comprising the kinases themselves, "[a] chimeric linker molecule

is prepared in which a 25 base pair oligonucleotide complementary to one of the anchors is crosslinked to a peptide substrate of a tyrosine phosphokinase enzyme." Felder at column 44, lines 18-21. Thus, Felder does not disclose the preparation of arrays comprising 61 purified active kinases or functional kinase domains thereof, as recited in present claim 1.

In reply, applicants' arguments as to Felder not disclosing the preparation of arrays are not commensurate in scope with the claims. While Shalon discloses an array of polynucleotide however, its mention, even only in passing of protein suffices the finding of obviousness.

The test for obviousness under 35 USC 103 is not the express suggestion of the claimed invention in any or all of the references but what the references taken collectively would suggest; and **inferences** which one skilled in the art would reasonably be expected to draw from the disclosure in the

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references. In re Preda, 159 USPQ 342 and In re Conrad, 169 UASPQ 170.

Nonetheless, Feder discloses an array of protein. Thus, at the time of applicants' invention array comprising either polynucleotide or protein kinase, whether a substrate or enzyme has been known in the art. One having ordinary skill in the art would reasonably expect to array a kinase since the prior art teaches that a substrate for the kinase has been spotted onto an array.

When a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. KSR v. Teleflex, 17 S. Ct. 1727, 82 USPQ 2d 1385 (2007).

### ***Double Patenting***

Claims 1-11, for example, is provisionally rejected on the ground of nonstatutory double patenting over claims 1, for example of copending Application No. 10/477329 ('329 application). This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending

application since the referenced copending application and the instant application are claiming common subject matter, as follows: the '329 claims disclose the same array as the instant array except the '329 claims do not claim the kinase array as instantly claimed. However, the disclosure of the '329 application discloses said array with kinase.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### ***Response to Arguments***

Applicants request that this rejection be held in abeyance until allowable subject matter is determined in the '329 Application and the presently claimed invention. At that time, Applicants may consider filing a Terminal Disclaimer. In reply, in the absence of a Terminal Disclaimer, the rejection is maintained. No claim is allowed.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action

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is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 12-16, 93-101, 106, 107, 112-133, 138-140, 142-159, 162, 165, 167, 171, 175 and 196-197, 16, 93-101, 106, 107, 112-133, 138-159, 162, 164-165, 167, 169-171, 173-175, 177, 178, 181-186, 188, and 193-197 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. D. Wessendorf/  
Primary Examiner, Art Unit 1639

<div><b><i>Application Number</i></b></div> <div></div>	<b>Application/Control No.</b>	<b>Applicant(s)/Patent under Reexamination</b>	
	09/849,781	SNYDER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	T. D. Wessendorf	1639	